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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,019

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EXAMINER

BADR, HAMID R

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,019	Applicant(s) ZIRZOW ET AL.	
	Examiner HAMID R. BADR	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE, 2/28/2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,33 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,33 and 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/27/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/2011 has been entered

The rejection of Claims 34 and 35 under 35 U.S.C. 112 second paragraph is withdrawn per applicants' cancellation of these claims.

Claims 32 – 46 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 32-33 and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 32 is indefinite for “comprising distillers grains which have been fermented with yeast” at section b and c. Since distiller’s grains are the grains remaining after the fermentation and distillation of alcohol, it is not clear whether the phrase is indicating an extra yeast fermentation on an already fermented grains.

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4. Claim 32 is indefinite for "blood sugar value". It is not clear whether "value" refers to the concentration of blood sugar or something else. It is normally understood that the concentration of blood sugar is decreased upon a treatment.

5. Claim 32 is indefinite for "thickening said distillers grains". It is not clear whether a concentration process is meant e.g. by removal of water or a thickening agent; e.g. a gum is added to thicken the composition.

6. Claim 32, at sections b and c, is also indefinite for "in an amount effective to lower said patient's increased blood sugar values". It is not clear whether the effect of administering the composition is instantaneous (i.e. like the effect of taking a pain killer) or the decrease of blood sugar level will be a gradual effect when the composition is taken for a period of time.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Tolle (WO/2001/010245, US 6,706,294 is an English equivalent of this publication; hereinafter R1).

8. R1 discloses the full process of fermenting the distiller's grains with yogurt or butter cultures. The processing steps are disclosed as presently claimed in claim 38. (col. 1, lines 22-37).

9. R1 teaches of dosing quantities of 21-25 grams to be effective doses. R1 discloses that 135 g of the fermented mass having 17% dry matter would provide the required dose. R1 then teaches of mixing the effective dose with other foods including

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milk preparations that can be presented in portions of 200-250 g ready to consume units. (col. 1, lines 50-60).

10. R1 discloses that the fermented product is suitable for diabetics (col. 2, line 11), for slimming cures, for recovery after operations, for dietetic foods, for the treatment of amino acid deficiency, for pancreatic functional disorders, carbohydrate addiction diseases, for intestinal functional disorders (col. 2, lines 55-61), for diabetics and weight reduction (col. 2, lines 47-48).

11. R1 discloses the inventive product can also be used as a supplementary diet during slimming cures (col. 2, lines 55-56). The consumption of the product as a food supplement as disclosed by R1 (col. 3, lines 10-15) is also an indication that the product is consumed on a steady basis for a period of time. It is clear that as a supplement the preparation would be consumed for a predetermined period of time during which the blood sugar level as well as blood triglyceride level would decrease therefore, the method as presently claimed would be inherent in the consumption of the fermented preparation when used as a supplement.

12. Given that R1 discloses utilizing the fermented distiller's grains for the reduction of diabetic effects (i.e. reducing blood sugar level) and weight reduction, and clearly both of these abnormalities are long term health problems, the reduction of effects will also be a long term issue for which a long term consumption of the fermented product is anticipated. The long term consumption of the product will be in fact the method as presently claimed.

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13. R1 discloses that it is possible to provide the product with further fermentable additives such as lecithins, honey, soybean proteins. (col. 2, lines 27-30).

14. R1 also discloses the incorporation of the fermented product into food supplements. (Claims 9- 11).

15. It is noted that Claim 32 has been amended to recite certain procedures to determine if a subject is in pre-diabetic state or is a true diabetic individual. The overall result would be determining if an individual has high blood sugar. It appears that these procedures are preliminary stages of carrying out a clinical study of the effect of the fermented distillers grains. It is then clear that such procedures would not add weight to the patentability of a product which is anticipated by R1. The disclosure by R1, referring to 'diabetics' implies that the food/supplement is beneficial to individuals with high blood sugar. Such individuals have already been diagnosed with the disease; i.e. diabetes and the procedures which are now recited in claim 32 have already been applied to those individuals.

Response to Arguments

Applicants' arguments are not persuasive for the following reasons.

1. Applicants argue that R1 does not provide a link between the administration of the double fermented grain and treating diabetes.

a. R1 clearly discloses the usefulness of their inventive product for diabetic people, for overweight people etc. R1 further teaches of using the product as a supplement which means that the product be consumed on a regular basis at least for a certain period of time. R1 also discloses effective dose of the product. It is clear that

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dose is only given for the functionality of a composition. It is clear that the lowered blood sugar and lowered triglyceride levels will be inherent to the consumption of the product on a regular basis; i.e. taking the composition as a supplement as disclosed by R1. The net effect will be the method as presently claimed.

2. Applicants argue that R1 mentions that the food is good for diabetics and is suited for diabetics due to the low amount of sugar.

a. It is of course true that the composition of R1 is good for diabetics because of low sugar content. However, when consumed as a supplement, i.e. on a regular basis for a period of time, then the blood sugar lowering effect will be pronounced.

3. Applicants argue that the blood sugar decreasing effect is due to the composition and not due to weight loss.

a. R1 clearly discloses that the product is beneficial for slimming cures. It is clear that the product should be consumed for a period of time (e.g. weeks or months). The lowering of blood sugar in such individuals would be concomitant with losing weight. An identical product to what is disclosed by R1 is being claimed for these effects. The active(s) in the composition of R1 is (are) the same as the active(s) in the presently claimed product. It is clear that consumption of the product in the doses provided by R1, on a regular basis, will eventually bring about reduced blood sugar. The clinical study carried out by Applicants is nothing but administering the product for a period of time to individuals with high blood sugar level. This clinical study would be

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equivalent to the disclosure of R1 stating that the composition can be a supplement; i.e. something which is recommended to be taken for a period of time.

Applicants are referred to the following passage.

PROCESS OF USE CLAIMS — NEW AND UNOBVIOUS USES OF OLD STRUCTURES AND COMPOSITIONS MAY BE PATENTABLE

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). **However, when the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated.** In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7- 10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). See also In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. “While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition.” 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1781

Hamid R Badr
Examiner
Art Unit 1781